

46851-1

7/6/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL -6 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Lawrence E. Culleen
Certol International
6120 East 58th Avenue
Commerce City, CO 80022

Subject: **Omni II**
EPA Registration No.: 46851-1
Application Date: June 6, 2014
Receipt Date: June 6, 2014

Dear Mr. Culleen:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c) 9.

Proposed Notification:

- Minor Label Revisions: 1) return use of previously approved signal words 2) indoor non-food use sites 3) add non-pesticidal claims

General Comment:

Based on a review of the material submitted, your notification to update as referenced above is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at hardy.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at grigsby.stacey@epa.gov during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Jacqueline Hardy
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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NOTIFICATION
Date Reviewed: 2/16/14
Reviewed By: SGRIGSBY

[Kills 99.9% of] [viruses*] [and] [bacteria**] [in 1 minute]]

Omni II™

[Alternative Brand Names:] [ProSpray C-60™] [Vital Defense®-D] [ProPhene™ plus]
[Concentrated] [Surface Disinfectant] [,] [Cleaning] [and] [Holding Solution]

["One-Step"] [Cleaner] [/] [Disinfectant] [/] [Deodorizer]

[The descriptive terms below are to be used, as applicable, depending on the microorganisms listed in the Effective Against Section.]

[Tuberculocidal] [,] [Virucidal*] [,] [Bactericidal] [,] [Fungicidal]

[Kills Staphylococcus aureus - MRSA HA [in one minute]]

Active Ingredients

| | |
|-----------------------------------|--------|
| o-phenylphenol | 9.0% |
| o-benzyl-p-chlorophenol | 1.0% |
| Inert Ingredients | 90.0% |
| Total | 100.0% |

E.P.A. Reg. No. 46851-1
E.P.A. Est. No. 46851-CO-003

[Lot #] [and] [expiration date] [printed on container]

Contents: [1 Quart] [(32 oz.) [-] [946 ml.]]
[Reorder No: _____]

Keep Out of Reach of Children

DANGER

Do Not Take Internally

[See other panels for additional precautionary statements.]

[PRODUCT BARCODE:] [+H816_____]

FIRST AID:

IF SWALLOWED: Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for further treatment advice.

THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING
Statements in brackets, [,] are optional or instructional. Sequence of statements is optional unless specified in 40 CFR 156.10. Capitalizing, pluralizing, singularizing, bolding, italicizing and abbreviation are variable unless specified in 40 CFR. Lists of uses and use sites may be used partially or in their entirety.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.

In case of an emergency for additional information call toll free 1-800-535-5053. Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS:

Hazardous to humans and domestic animals.

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Harmful if inhaled, swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles, face shield, or safety glasses, and protective clothing (long-sleeved shirt and long pants, socks, plus shoes and chemical resistant gloves such as water proof gloves). Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

USER SAFETY REQUIREMENTS: Follow manufacturers' instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. [Users must wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.] Users must remove clothing immediately if pesticide gets inside. Wash thoroughly and put on clean clothing.

[Listing of at least one of the following equipment/instruments/hard, non-porous surfaces on production labels are required. The last equipment/instrument/hard, non-porous surface listed will be preceded with the word "and".]

Omni II™ is [a] [an] [effective] ["one-step"] [cleaner] [and] [broad-spectrum] [disinfectant] [according to the AOAC Use-Dilution Test] [,] [modified in the presence of 5% organic soil load] [and] [meets AOAC efficacy standards for hospital-use disinfectants.] [It [cleans] [,] [disinfects] [and] [deodorizes] [hard non-porous surfaces] [in one labor-saving step].] [Omni II™ may be used in [healthcare,] [office,] [transport,] [commercial] [and] [home settings] [on] [vinyl,] [plastics,] [metals,] [floors,] [walls,] [counters,] [carts] [and] [bedside equipment].]

[Omni II™ is effective against the following microorganisms on hard non-porous surfaces when used as directed:]

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[EFFECTIVE AGAINST:]
[MYCOBACTERIUM TUBERCULOSIS VAR. BOVIS ((TB))]
[STAPHYLOCOCCUS AUREUS]**
[STAPHYLOCOCCUS AUREUS - MRSA HA]**
[SALMONELLA ENTERICA]**
[PSEUDOMONAS AERUGINOSA]**
[HIV-1 ((AIDS VIRUS))*]
[HERPES SIMPLEX VIRUS TYPES 1 & 2*]
[TRICHOPHYTON MENTAGROPHYTES ((FUNGUS))]

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

[The following paragraph will be included in its entirety when the production label references healthcare use.]

Omni II™ is designed for use on hard non-porous surfaces and/or in holding solution. This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

CLEANING: [Omni II™ is an effective cleaning agent.] [Prepare [a fresh 1:32 use solution of] Omni II™ and apply directly to surface using [spray] [bottle] [or] [mop]. Wipe surface to remove debris and solution using [clean] [paper] [or] [cloth] [towels] and discard. [Occasional [rinsing] [or] [wiping] [with] [damp] [cloth] is recommended when Omni II™ is used frequently [on [floors,] [stainless steel,] [vinyl] [and] [other surfaces].]

[MEDICAL AND DENTAL INSTRUMENT HOLDING SOLUTION and ULTRASONIC INSTRUMENT CLEANING DEVICES: Prepare [a 1:32 use solution of] Omni II™ in [holding container] [or] [ultrasonic cleaning device]. [[Soak] [or] [operate device] [for 5 minutes.] Rinse articles thoroughly with potable water and pat dry. Package and sterilize instruments prior to use. The efficacy of the solution is compromised in the presence of organic matter. Prepare a fresh solution [daily] [or] [change] [more often] [if it becomes [diluted] [or] [soiled]. [Effective in waters up to 400 ppm hardness calculated as calcium carbonate.] [For use on [metals] [,] [plastics] [,] [rubber] [and] [glass].] [Glass may etch over prolonged or repeated exposure to concentrated solutions.] [Do not store lensed articles in concentrated Omni II™.]]

[FOR CLEANING HAIR CLIPPERS AND ELECTRIC SHEARS: While [clipper] [/] [electric shear] is running, hold [clipper] [/] [electric shear] in downward position and spray [a prepared 1:32 use solution of] Omni II™ to thoroughly wet the blades. [Avoid spraying on the [clipper] [/] [electric shear] case or dripping into the [clipper] [/] [electric shear] housing.] Rinse [clipper] [/] [electric shears] and follow with [appropriate] [lubricating] [and] [disinfection] [process].]

[FOR CLEANING SALON IMPLEMENTS AND SHEARS: Spray [with prepared 1:32 use solution of] Omni II™ to thoroughly wet the [implement] [or] [shear]. [Wipe away visible debris using [a] [soft] [bristle] [brush] [or] [cloth]]. Rinse [implement] [or] [shear] and follow with [appropriate] [lubricating] [and] [disinfection] [process].]

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DISINFECTION: Apply [1:32 use solution of] Omni II™ to hard non-porous surfaces [such as floors,] [walls,] [counters] [and] [tables] [with [mop] [or] [spray] [using [clean] [paper] [or] [cloth] [towel]]]. All surfaces must remain wet for one minute. [Use a five minute contact time to inactivate TB.] Allow to air dry or remove excess with [clean] [mop] [,] [cloth] [or] [sponge]. For heavily soiled areas, a pre-cleaning step is required. [Omni II™ may be used for this purpose.] [Prepare a fresh solution [daily] [or] [change] [more often] [if it becomes [diluted] [or] [soiled when used [in [buckets,] [soak pans] [and] [ultrasonic] [instrument cleaning devices].] [A properly prepared solution of Omni II™ has a use life of 60 days after dilution when stored in a closed container such as a spray bottle.] [[Wipe] [or] [rinse] surfaces periodically after disinfection.]

CONTACT TIME:

[ONE MINUTE EXPOSURE:]

[Staphylococcus aureus] [,] [Staphylococcus aureus - MRSA HA] [,] [Salmonella enterica] [,] [Pseudomonas aeruginosa] [,] [HIV-1] [(AIDS virus)] [,] [Herpes simplex virus types 1 & 2] [,] [Trichophyton mentagrophytes] [(Fungus)]

[FIVE MINUTE EXPOSURE:]

[Mycobacterium tuberculosis var. bovis] [(TB)]

[FOR USE AS A DISINFECTANT ON PRECLEANED NON-CRITICAL MEDICAL DEVICES, INSTRUMENTS AND IMPLEMENTS: [Instruments must be thoroughly cleaned to remove excess organic debris [Omni II™ may be used for this step], rinsed and dried. Apply Omni II™ to pre-cleaned surfaces, thoroughly wetting areas to be disinfected. Allow surfaces to remain visibly wet for 5 minutes at room temperature [(68°F / 20°C)]. Rinse instruments and wipe dry prior to use.]]

TO PREPARE 1:32 USE DILUTION

To Make:

1 Pint

Water 15 ½ fluid oz.

Omni II™ ½ fluid oz. (15 ml)

1 Quart

Water 31 fluid oz.

Omni II™ 1 fluid oz. (30 ml)

½ Gallon

Water 62 fluid oz.

Omni II™ 2 fluid oz. (60 ml)

1 Gallon

Water 124 fluid oz.

Omni II™ 4 fluid oz. (120 ml)

[The following HIV instructions are to be included on production labels when claims against HIV are listed.]

Omni II™ kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type-1 HIV-1 [(associated with AIDS)].

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SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids, always wear items such as disposable gloves, gowns, masks and eye coverings.

CLEANING PROCEDURES: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of Omni II™. [Omni II™ may be used for this purpose.]

CONTACT TIME: Allow surface to remain wet for one minute to kill [HIV-1 [(AIDS Virus)]], [Staphylococcus aureus] [,] [Staphylococcus aureus - MRSA HA] [,] [Salmonella enterica] [,] [Pseudomonas aeruginosa] [,] [Herpes simplex virus types 1 & 2] [and] [Trichophyton mentagrophytes [(Fungus)]. [Use a five minute contact time for Mycobacterium tuberculosis var. bevis [(TB)].]

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids must be autoclaved and/or disposed of according to local regulations for infectious waste disposal.

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container in an area inaccessible to persons unfamiliar with its use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. **Triple rinse (or equivalent) promptly after emptying.** Discard rinsate in accordance with Pesticide Disposal instructions. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by procedures approved by state and local authorities.

[Optional Marketing Claims:]

[Lemon Scent.]

[Fresh Scent.]

[AREAS OF USE:]

[NURSING, HOSPITAL AND HEALTHCARE SETTINGS:]

[[Ambulatory Surgical Centers]][(ASC)]

[Anesthesia]

[Cat Labs]

[CCU]

[Central Supply Clinics]

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[NURSING, HOSPITAL AND HEALTHCARE SETTINGS (continued):]

- [Clinics]
- [Dental Offices]
- [Dialysis]
- [Doctors' Offices]
- [Donation Centers [(Apheresis, Blood, Milk, Plasma, Semen)]]
- [Emergency Medical Settings]
- [Emergency Rooms]
- [Endoscopy Centers]
- [Eye Surgical Centers]
- [GI Centers]
- [Hospices]
- [ICU]
- [Isolation Areas]
- [Laboratory]
- [Laundry Rooms]
- [[Operating Rooms][(OR)]]
- [Ophthalmic Offices]
- [Orthopedics]
- [[Out-patient Surgical Centers][(OPSC)]]
- [Patient Care Areas]
- [Physical Therapy]
- [Radiology]
- [Reception Areas]
- [Recovery Rooms]
- [Rehabilitation]
- [Respiratory Therapy]
- [Surgery]
- [Waiting Room]

[OFFICE AND HOME SETTINGS:]

- [Libraries]
- [Manufacturing Facilities]
- [Office Buildings]
- [Public Facilities]
- [Schools]
- [Cabinets]
- [Computers]
- [Counters]
- [Desks]
- [Doorknobs]
- [Fax Machines]
- [Filing Cabinets]
- [Garbage Cans]
- [Hard Surfaces on Headsets]
- [Keyboards]
- [Public Telephones]
- [Railings]
- [Seats]
- [Sinks]
- [Tables]
- [Tabletops]
- [Telephones]
- [Work Stations]

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[EMERGENCY SERVICES SETTINGS:]

- [Ambulances]
- [Police Cars]
- [Transport Vehicles]

[VETERINARY SETTINGS:]

- [Isolation Areas]
- [Veterinary Clinic]
- [Waiting Room]

[HEALTH CLUB FACILITIES AND GYMS:]

- [Gym Equipment]
- [Locker Rooms]
- [Reception Areas]
- [Showers]

[SALONS, ESTHETICIANS, BARBER SHOPS:]

- [Beauty Shops]
- [Manicure Salons]
- [Spas]

[TATTOO PARLORS:]

[BATHROOMS:]

- [Basins]
- [Bathroom Fixtures]
- [Bathtubs]
- [Cabinets]
- [Countertops]
- [Doorknobs]
- [Faucets]
- [Glazed Tiled Walls]
- [Hampers]
- [Handles]
- [Handrails]
- [Showers]
- [Sinks]
- [Toilet [(Handle, Rim, Seats, Tank, Other Exterior Surfaces)]]
- [Urinals [(Exterior Surface)]]
- [Vanity Tops]

[TRANSPORT SERVICE SETTINGS:]

- [Fire Trucks]
- [School Buses]
- [Transport Vehicles]
- [Hard Plastic or Metal Flooring]
- [Seats]
- [Steering Wheel]
- [Walls]

[HARD NON-POROUS SURFACES:]

- [Adapter Rings]
- [Bed Frame]
- [Bidet]
- [Hard Surfaces on Booster Seats]
- [Brass]
- [Brushes]
- [Chrome]
- [Clean-up Carts]
- [Clipper Blades]

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[HARD NON-POROUS SURFACES (continued):]

- [Combs]
- [Copper]
- [Crystal]
- [Cuspidors]
- [Dental Chairs]
- [Dental Units]
- [Digital X-Ray Sensors]
- [Drains]
- [Dressing Carts]
- [Drinking Fountains]
- [Electric Shears]
- [Enamel]
- [Examination Tables]
- [Fixtures]
- [Floors]
- [Furniture [(Non Wood)]]
- [Glass]
- [Glazed Ceramic Tile]
- [Glazed Porcelain Tile]
- [Grocery Cart Handles]
- [Grocery Cart Child Seats]
- [Hair Care Implements]
- [Hair Clippers]
- [Laminate]
- [Lamps]
- [Light Switches]
- [Linen Carts]
- [Linoleum]
- [Litter Boxes]
- [Manicure Implements]
- [Manicure Tables]
- [Marble [(Culture, Synthetic)]]
- [Marlite]
- [Metal]
- [Metal Blinds]
- [Mirrors]
- [Nail Implements]
- [Non-Porous Dental Impression Material]
- [Outdoor Furniture]
- [Parquet]
- [Patient Chairs]
- [Pens]
- [Plastic]
- [Plastic Mattress Covers]
- [Portable Toilet]
- [Recycling Bins]
- [Remote Controls]
- [Resilient [(Ceramic)] Floor]
- [Salon Surfaces]
- [Sealed Granite]
- [Sealed Wood]
- [Shears]

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[HARD NON-POROUS SURFACES (continued):]

- [Sports Equipment]
- [Stainless Steel]
- [Stretchers]
- [Tin]
- [Tools]
- [Vinyl]
- [Wheelchairs]
- [Whirlpool Interiors]
- [Windows]

[HARD NON-POROUS USE SITES:]

- [Attic]
- [Automobile]
- [Basement]
- [Bathroom]
- [Bedroom]
- [Boat]
- [Cabin]
- [Camper]
- [Closet]
- [Den]
- [Dining Room]
- [Dorm]
- [Family][/][Living Room]
- [Garage]
- [Home]
- [Kitchen]
- [Laundry Room]
- [Locker]
- [Mobile Home]
- [Mudroom]
- [Pet Area]
- [Public Places]
- [Storage Area]
- [Studio]
- [Sunroom]
- [Tool Shed]
- [Workshop]

[HARD NON-POROUS PROFESSIONAL USE SITES:]

- [Barber Shops]
- [Beauty Shops]
- [Blood Bank]
- [Clinic]
- [College]
- [Commercial Building]
- [Correctional Facilities]
- [Dental Office]
- [Doctors' Office]
- [Grocery Store]
- [Gymnasium]
- [Health Care Facility]
- [Health Club]
- [Hospital]

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[HARD NON-POROUS PROFESSIONAL USE SITES (continued):]

- [Hotel];[Motel]
- [Kennel]
- [Laboratory]
- [Laundromat]
- [Libraries]
- [Manicure Salons]
- [Manufacturing Facilities]
- [Military Installation]
- [Morgues]
- [Mortuaries]
- [Nursing Home]
- [Office Building]
- [Patient Room]
- [Pharmacy]
- [Public Places]
- [Recreational Center]
- [Restroom]
- [Salon]
- [Schools]
- [Shelter]
- [Sick Room]
- [Spas]
- [Tattoo Parlors]
- [Veterinary]
- [Warehouse Club]

[Omni II™ is recommended for use in healthcare settings.]

[Omni II™ is intended for use [on] [/] [in] medical [devices] [/] [settings].]

[Omni II™ is a multi-purpose [disinfectant][/][decontaminant] [cleaner] for use on hard non-porous inanimate surfaces.]

[Omni II™ will effectively clean and disinfect, when used as directed, such items as [list].]

[Non-critical medical devices are items that come in contact only with intact skin.]

[Omni II™ is an effective method to clean against odor-causing organisms on hard non-porous surfaces listed on this label.]

[Non-alcohol actives]

[Indicated for use when manufacturer's instructions recommend avoiding alcohol [on] [vinyls] [or] [plastics].]

[No bleach actives]

[Water-based intermediate-level disinfectant]

[Broad based material compatibility]

| |
|--|
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|--|

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[The following statement is to be included on production labels when food contact areas or surfaces are listed:]

[A thorough rinse with potable water is required for surfaces in direct contact with food.]

Certol®

International

A Limited Liability Company

6120 East 58th Avenue
Commerce City, CO 80022 USA
Toll-free: (800) 843-3343
www.certol.com

[OMN2/EPA/TX05 05/14]

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